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Description of the Concept of Medical Technologies and Devices in Latvia in the Context of Robotics

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Abstract

Nowadays one of the topical issues, from legal point of view, is technologies and robotics technologies and devices. Technologies and robotics technologies and devices have become dominant in various areas including business, banking sector and healthcare. Technologies influence every aspect of daily life of modern society at home and work. Technologies, considering development of robotics, have a huge potential to transform public and private sectors. They provide modern and safe levels of services in various forms. The impact of technologies and robotics technologies will grow over time [11]. The article is devoted to definition of legal study of technologies and medical technologies and correlation between particular definitions with the definition of robotics in Latvia. General conclusions related to legal study of the subject shows lack of correct definition of medical technologies and unclear understanding of robotics technologies, artificial intelligence based medical devices from medical care perspective.

Keywords: medical technologies, robotics, rights.

Introduction

The development of technologies shows huge progress in various areas, and healthcare is one of the most advanced ones where technologies work hand in hand with humans. Nowadays the issue of technologies and development of particular segment is

vital for future from the legal point of view. Advanced medical technologies such as artificial intelligence, VR/AR, 3D-printing, robotics or nanotechnology came in with a huge potential. The question remains about the legal regulation and interpretation of existing legal regulations in the area of medical technologies, devices from robotics perspective [11]. Medical devices have a fundamental role in healthcare by providing innovative solutions for prevention, monitoring, prediction etc. [3] National and international regulations of particular area have several approaches to support the development of technologies in healthcare [9]. The problem is to identify whether there is a difference between the definition of medical technologies, robotics technologies and devices in Latvia.

In Latvia, detention of medical devices is included in Medical Treatment law Section 2. The aim of the law is to govern public relationships in medical treatment in order to ensure qualified prophylaxis and diagnosis of diseases or injury, and also qualified medical treatment and rehabilitation of patients, and to determine special legal regulation provisions for economic activity of medical treatment institutions [5]. According to the medical technologies' detention given by the law, medical technologies are methods to be applied in medical treatment, medical devices and medicinal products [5]. The stated indicates that the definition consists of three important elements: medical treatment, medical devices and medical products. It means that the definition of medical technologies provides the area of interpretation using three elements mentioned before.

Results and Discussion

The definition states that medical treatment is part of medical technologies. However, a boarder interpretation of this has to be made. Medical treatment includes both individual medical devices with instructions for their use and a whole set of methodologies, for example, the method used in treatment is laser therapy etc. [2]. It means that the methods used in treatment should be seen as a set of medical and diagnostic activities of medical nature. Medical products, according to Pharmaceutical Law article 1 paragraph 17, are any substance or combination of substances which present properties that are needed in order to provide medical treatment for human and animal diseases. As well as to perform prophylaxis of such diseases, and any substance or combination of substances, which may be utilised or administered to humans or animals with the aim to either restore, correct or change physiological functions causing pharmacological, immunological or metabolic effects or make medical diagnosis [1].

Nevertheless, according to the Medical Treatment law Section 1 article 21, medicinal devices are all tools, appliances, devices, software, materials or other items which are used separately or together with other devices, including together with a software which the manufacturer thereof has intended for use in medical treatment in order to diagnose, prevent, monitor and heal illnesses or ease the course thereof, to diagnose, monitor, heal, ease or compensate injuries or physical deficiencies, to research, replace or change human anatomy or physiological processes, to control insemination and which

the intended basic activity on a human body surface or in a human body do not achieve by pharmacological, immunological or metabolic means, but it is possible to help to ensure functioning of a medical device with such means [5].

The use of particular medical technologies in medical treatment are confirmed by national regulations [1].

In accordance with Section 2 of the regulations, medical technologies are evaluated and approved by the Latvian State Agency of Medicines. The Agency approves medical technologies and makes registration of particular technologies in the database of medical technologies. It must be noted that there are several restrictions. The agency does not register technologies that describe a medicinal product which is used in accordance with the type of use specified in the instructions for use of the medicinal product and approve it in accordance with the regulatory enactments regarding the registration of medicinal products. It does not also register the devices that describe medical devices which are used in accordance with the type of use specified in the instructions for use and approved in accordance with the regulatory enactments regarding the registration of medical devices [12].

Medical devices are one of the many types of products that, like medicines, cosmetics, nutritional supplements, etc. products are available in Latvia. Only devices intended by the manufacturer for medical use – for prevention, diagnosis, monitoring, treatment of diseases – are considered to be medical devices. Medical devices (excluding medical devices used for in vitro diagnostics) are divided into the following classes: Class I, II a, II b and III medical devices as well as active implantable medical devices [12]. It is essential to identify and distinguish in vitro diagnostic devices from the common range of medical devices, in accordance with Article 7 of *Regulation* (EU) *2017/746 of the European Parliament and of the Council* of 5 April 2017 on *in vitro* diagnostic medical devices, which states that the scope of application of this Regulation should be clearly delimited from other legislation concerning products, such as medical devices, general laboratory products and products for research use only [11].

As mentioned, the issue of medical technologies in included in particular national regulations [1]. The regulation issued in accordance with Medical treatment Law.

There are no significant shortcomings in the regulation of medical technologies. With the amendments of 2019 on the basis of reorganisation, a rational decision was made, the effectiveness of which is too early to judge, as a relatively short period of time has elapsed since The State Agency of Medicines of Latvia took over the functions of The National Health Service. In qualification of responsibility, in the Authors' opinion, the issue has been solved, but with the greater involvement of the financial capacity institution, there is a reason to consider the entrusted functions to be realised as well. Medical technology is a set of tools for multi-profile healthcare that is based on scientific knowledge and for approval of which a specific process has been established.

With regard to medical devices, in accordance with Article 34 of Medical Treatment law, the head of a medical treatment institution is directly responsible for compliance

with the regulations issued by the Cabinet of Ministers. In its turn, in accordance with the Cabinet of Ministers regulations No 689 on the Procedure for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices, Section 163 [1], the head of a medical institution is responsible for compliance with these regulations in the medical institution, as well as for observance of the developed and introduced in the medical institution system of medical devices operation. In the context of determining liability, in the event of adverse consequences, it is important to note that Article 195 of the regulations provides that the manufacturer of a medical device is fully responsible for carrying out the necessary investigative actions in case of an accident, regardless of the location of accident detection and investigation, providing a time reference schedule starting from the time of manufacturer notification. The manufacturer shall send the initial report to The State Agency of Medicines of Latvia immediately.

However, according to Article 3 of the regulations The State Agency of Medicines of Latvia receives and stores information on the manufacturers of medical devices with a place of business in LV and medical devices manufactured by them, issues permits for the purchase of specially supplied medical devices without CE marking, receives, reviews and stores information received during the medical device notification procedure and performs vigilance of medical devices. Nevertheless, in accordance with Article 4 of the regulations, the Health Inspectorate of Latvia monitors and controls observance of requirements set out for medical devices. The Health Inspectorate of Latvia, as a market surveillance authority, supervises the market of medical devices, as well as controls devices in operation. At the same time, in accordance with Article 5 of the regulations, the conformity of medical devices is assessed by a body accredited by a national accreditation body in accordance with the legislation on assessment, accreditation, supervision of conformity assessment bodies and which is notified to the European Commission in accordance with legislation on the procedure for establishment of a notification body and on the procedure for taking a decision and notifying the European Commission of conformity assessment bodies performing conformity assessment in the regulated field or a conformity assessment body for medical devices notified by other European Union member states.

Problems arise in the regulation for medical devices. As mentioned above, the basic problem of the regulatory framework is related to insufficient legal supervision and insufficient setting of criteria. Which is proved by the need to implement a new regulations No 2017/745 and No 2017/746. The need for stricter state supervision will result in additional responsibilities both in increasing the responsibility of state institutions in the implementation of supervision functions, and in the obligations of medical devices developers to provide additional evidence to certify the safety of inventions.

Currently the European sector of medical devices is facing major changes in connection with the full entry into force of the regulations. Prior to drafting of the regulations, each country interpreted and applied the general principles and criteria set out in the directive for certification and supervision of medical devices in different ways. The different approaches did not contribute to the common goal of safe and transparent

use of medical devices in society. In addition, a different approach served to undermine public confidence in the safety of medical devices.

The single framework will harmonise Member States' approaches in the sphere of medical devices by providing stricter monitoring mechanisms and reducing administrative burdens for manufacturers by reducing the need for multiple submissions. In addition, a common EUDAMED system will be provided, which will bring together all EU medical devices in one place, ensuring a more convenient and efficient implementation of control functions and providing public access to the system data. At the same time, EUDAMED will contain:

1) Electronic business registration system;
2) Device unique identification system;
3) Devices registration electronic system;
4) Electronic system of notified bodies and certificates;
5) Electronic clinical trials system;
6) Electronic vigilance and after-market monitoring system;
7) Electronic market surveillance system [6].

In this way, implementation of regulations and application of the EUDAMED system will lead to a clearer, faster and more accurate flow of information. The functioning of notified bodies, market surveillance functions will be improved, more specific and detailed requirements for medical devices and related products will be set forward; for example, the use of clinical data, transparency of medical device information will be ensured and international coordination between EU institutions and Member States will be enhanced.

Unlike the medicines regulatory system, national competent authorities do not register medical devices before they are placed on the market in Ireland or Europe. The regulatory framework for medical devices involves notified bodies (independent technical organisations, many of which operate commercially) that assess medical devices throughout the EU and affix the CE marking if they are allowed to be placed on the market. This system is designed to take into account the huge number of different devices and different technologies, while maintaining regulation through market supply and demand [9].

From a legal point of view, it would also be useful to set up a single EU medical device monitoring unit capable of carrying out independent inspections and monitoring of all medical devices. This would ensure the full rights of consumers (patients) to safe medical devices. Starting from a single framework to the application of uniform evaluation and certification criteria. Of course, considering the economic aspect, establishment of such an institution would require significant human and financial resources, but, in the Authors' opinion, it is feasible. Given that there is a body at national level in each European Union Member State to which the supervision of medical devices is delegated, it is possible to provide the necessary training for relevant staff and to set up a single European Union body to perform the same supervisory functions in the interests of entire European Union. The Authors believe that such a single EU body will not be able to perform technological assessment of all medical devices on a permanent basis;

therefore, such a body would need direct, wide-ranging cooperation with multi-profile scientific institutions. In the Authors' opinion, such a model would reduce the possible risks of fraudulence, when the invited commercial institution would act as a specialist in the examination of the specific technology. In turn, the issue of funding would be solved by the participation fee of each Member State (reducing the need for supervision of national medical devices by transferring the relevant funding for the maintenance of institutions to the budget of the joint institution) [8].

As mentioned above, medical technology sector is often considered to be one of the most innovative sectors. The European regulatory framework is generally considered to have the aim to promote a favourable environment for product innovation. The main priority is to provide a regulatory framework that is strong and consistent enough to ensure that innovation is safe and timely, and the new regulatory framework should facilitate this. This sector continues to expand rapidly, especially in the following areas:

1) more and more combined products are being created, where medical device technologies are combined with medicines, tissues, cells and genetic therapies;
2) new programmes and digital health technologies are being developed to make diagnoses, help make clinical decisions and monitor health;
3) new production techniques, such as 3D printing, provide wider access to health-care products and allow them to be better tailored to individual needs [6].

The Authors conclude that in accordance with the content of Regulation No 2017/745, the norms do not distinguish between automated, semi-automated or independent medical devices. At the same time, it follows from the definition of the Regulation that the provisions of the Regulation apply to all medical devices (including robotics and MI technologies that are applicable to medical care). On the other hand, Part 12 of the Regulation provides that devices which are also machinery within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC which falls within the scope of the mentioned Directive also complies with the essential health and safety requirements set out in Annex I to that Directive, to the extent that those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation. According to Article 35 of the Regulations, if a medical device is a machine, it is subject to not only provisions of Section 3.2 of these Regulations within the meaning of the legislation on the safety of machinery, but also essential requirements for the safety of machinery and risk analysis [7].

In its turn, the Cabinet of Ministers Regulation No 195 on Safety Regulations for Machinery is the norms incorporated in Directive 2006/42/EC of the European Parliament and of the Council on machinery, and amending Directive 95/16/EC. According to Directive No 2006/42/EC and Cabinet of Ministers Regulation No 195 "machinery" means (at least one of the definitions:

1) an assembly of connected parts or components for a special purpose, at least one of which is movable, fitted or intended to be fitted with a propulsion system which does not directly use human or animal force;

2) an assembly referred to in the first indent, which lacks only the components necessary to secure it in place or to connect it to energy and propulsion sources;
3) an assembly referred to in the first and second indents, which is ready for installation and can function in that condition only if it is mounted on a vehicle or installed in a building or structure;
4) assemblies consisting of the machinery referred to in the first, second and third indents or of the partly completed machinery in which, for achievement of one purpose, machinery is arranged and operated in such a way that it functions as a single unit;
5) an assembly consisting of parts or components joined together for the purpose of lifting loads and / or persons, at least one of which is moving, and the only source of energy being directly applied human power [4].

It follows from the regulatory context that, for example, certain robotic medical devices, namely a wheelchair, by means of which a patient moves, also qualify as both a machine and a medical device, and will therefore be subject to the obligations imposed by both regulations. On the other hand, it can be concluded from the content of Directive No 2006/42/EC and Regulation No 2017/745 that the norms do not regulate robotics technologies and related issues, as the regulation does not provide legal norms on data to be used in technology operation, nor other tools and values, used in robotics technology. In case of robotic equipment, provisions of that Directive may apply only in certain cases, such as an automated mobility device [4]. Given that currently there is no specific regulation on robotics, provisions of this directive (which are integrated at national level) are the closest legal framework that currently exists.

Conclusion

Technological development creates both new medical devices, for qualification and testing of which the existing criteria are applicable, and such technologies, for the application of which in medicine there are no analogues and for the identification of which new criteria and separate regulatory regulations are required. Consequently, the Authors see a loophole in the legal framework in the field of medical devices, which should be addressed in view of technological innovations expected in the near future, because although the developed rules in the form of regulations has not yet entered into force, it is clear that the norms contained in the regulations will not be sufficient to regulate the most complex future technologies, such as MI.

Technologies considering development of robotics has a huge potential to transform public and private sectors. In Latvia, considering current legal documents and European Union documents there are several problems in the field of legal definitions mentioned before.

The local legal regulation must be improved considering huge progress in medical technologies and robotics. Unclear understanding of robotics technologies, artificial intelligence-based medical devices, medical technologies leads to incorrect applicability

of current legal documents in practical cases. It is necessary on national level to review the national legal documents, rules and introduce a new definition in the field of medical technologies, devices etc. The explanation of robotics and Artificial intelligence-based technologies must be included in legal documents.

Medicīnisko tehnoloģiju un ierīču jēdzienu raksturojums Latvijā robottehnoloģiju kontekstā

Kopsavilkums

Raksts veltīts sabiedrībai aktuālas tēmas izpētei – par straujās tehnoloģiskās attīstības iespaidā radīto jauno robotisko un mākslīgā intelekta vadīto ierīču izmantošanas regulējuma nepieciešamību tiesību subjektu tiesisko attiecību sakārtošanai. Rakstā analizēts veselības aprūpē izmantojamo daudzfunkcionālo iekārtu lietošanas tiesiskais regulējums, kā arī tā ietekme uz pacientu tiesību ievērošanu.

Robotikas tehnoloģijas un ierīces tiek aktīvi izmantotas veselības aprūpes procesā, it īpaši diagnostikā. Šīs tehnoloģijas ietekmē gandrīz visus mūsdienu sabiedrības ikdienas aspektus un ir kļuvušas par dominējošām dažādās jomās, tostarp uzņēmējdarbībā, banku sektorā un veselības aprūpē. Ņemot vērā robotikas attīstību, šīm tehnoloģijām ir milzīgs potenciāls gan publiskajā, gan arī privātajā sektorā. Laika gaitā robotikas tehnoloģiju ietekme pieaugs, un pieaugs arī tiesiskā aspektā pētāmo problēmjautājumu klāsts.

Līdz ar to ļoti svarīga ir tehnoloģiju un medicīnas tehnoloģiju juridisko problēmjautājumu definēšana, korelācija starp konkrētām definīcijām, kā arī robotikas definīcija Latvijā. Vispārīgi secināms, ka medicīnisko tehnoloģiju jomā trūkst skaidru definīciju, kas sniedz nepārprotamu izpratni par robotikas tehnoloģijām, mākslīgā intelekta robottehnoloģijām, medicīnas ierīcēm u.c. Mūsdienās tehnoloģiju jautājums un konkrēta segmenta attīstība nākotnē ir būtiska no juridiskā viedokļa. Piemēram, attīstoties medicīnas tehnoloģijām, kas balstītas uz mākslīgā intelekta sistēmām, novērojams liels potenciāls diagnostikas kontekstā.

Taču tehnoloģiskais progress šobrīd ir daudz straujāks nekā jauno tiesību attīstība. Joprojām aktuāls ir jautājums par nākotnes tiesisko regulējumu un esošo tiesisko regulējumu, tā interpretāciju medicīnas tehnoloģiju, ierīču jomā. Medicīniskām ierīcēm, piedāvājot novatoriskus risinājumus profilaksei, novērošanai, prognozēšanai utt., ir būtiska loma veselības aprūpē. Nacionālajos un starptautiskajos tiesību aktos vērojamas vairākas pieejas, lai atbalstītu tehnoloģiju attīstību veselības aprūpē. Taču problēma ir noteikt, vai Latvijā pastāv atšķirība starp medicīnas tehnoloģiju, robotikas tehnoloģiju un ierīču definīciju. Jāatzīst, ka robottehnoloģiju, mākslīgā intelekta ierīču tiesiskais regulējums Latvijā šobrīd nav pilnīgs, kaut arī jauno robottehnoloģiju un mākslīgā intelekta ierīču izgudrošanas, ražošanas un pielietošanas iespaidā tiesiskā regulējuma pilnveides nepieciešamība arvien palielinās.

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